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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ISSAC, ROY P	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,765	OKU ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-15 and 17* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 8/02/2007, wherein claims 5-8 and 16 have been cancelled and claims 1-4, 9-15 have been amended, and claim 17 is newly submitted.

Amended claims 1-4 and 9-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 1-4 and 9-15 are directed to a method for lowering lipids in living body while the originally claimed invention was directed to a lipid regulating agent. The originally filed claims and the newly amended claims are related as products and process of use.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 9-15, drawn to a, method for lowering lipids in living body by the use of cyclic tetrasaccharide, ({→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and derivatives thereof).

Group II, claim(s) 17, drawn to a composition comprising the cyclic tetrasaccharide {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and derivatives thereof).

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common technical feature is the cyclic tetrasaccharide, {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and derivatives thereof. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. For example, Kubota et. al. discloses the preparation of the same tetrasaccharide and its use in food and pharmaceutical preparations. (WO 01/90338, Publication Date 11/29/2001; Of record;). English Equivalent, U.S. Patent No. 7,192,746 (Of record) is used *in lieu* of translation.

Since applicant has received an action on the merits for the originally presented invention, a lipid-regulating agent comprising said cyclic tetrasaccharide, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-4 and 9-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Withdrawn

In view of the cancellation of claims 5-8 and 16, all rejections made with respect to claims 5-18 and 16 in the previous office action are withdrawn.

The following is a new ground of rejection necessitated by applicants' amendments:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/565,069. Although the conflicting claims are not identical, they are not patentably distinct from each other because this application claims a lipid-regulating agent comprising a cyclic tetrasaccharide represented by the formula {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or its saccharide-derivative(s) as an effective ingredient, and the '069 application claims an accelerator for mineral absorption, which comprises an effective ingredient cyclic tetrasaccharide represented by {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof. Note that, the recitations "a lipid-regulating

agent", is considered as an intended use of the compositions claimed. Note that it is well settled that "intended use" of a composition or product, e.g., "a lipid-regulating agent", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Thus, claim 17 is deemed anticipated by claims 13-15 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13-15 recite a unit dosage form. Applicant's amendment with respect to the amendments reciting "unit dosage form" herein has been fully considered, but is deemed to insert new matter into the claims

since the specification as originally filed does not provide support for applicants' claim a unit dosage composition.

Consequently, there is nothing within the instant specification, which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the lowering cholesterol or lowering the amount of triglycerides in blood plasma does not reasonably provide enablement for regulating lipid or regulating the amount of lipids in human body or regulating the metabolism of lipoproteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The skilled artisan would view that the recitation, **regulating** the amount of lipids in human body or regulating the metabolism of lipoproteins, would reasonably encompass both increasing as well as lowering the amount of lipid in blood and lowering as well as increasing the metabolism.

The instant claims are drawn to a composition for regulating skin and regulating the metabolism of lipoproteins. The instant specification fails to provide information that

would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to compositions for regulating, i.e., encompassing both both increasing as well as lowering the amount of lipid in blood and lowering as well as increasing the metabolism.

The relative skill of those in the art: The relative skill of those in the art is high.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to use the composition herein to show how to increase as well as decrease the amount of lipid in blood or lower as well as increase the metabolism.

The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredicatable and undeveloped art. See MPEP § 2164.

The predictability or lack thereof in the art and the quantity of experimentation necessary:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses thousands of compositions with varying effects and unknown side effects. As such, each composition will need to be individually evaluated for activity.

The skilled artisan would view that, regulating, encompassing both increasing as well as decreasing the amount of lipid in blood or loweing as well as increasing the metabolism is highly unpredictable since the skilled artisan would not understand how the same compound or agent could increase and decrease the level of lipid in blood or how the same composition can increase as well as decrease the rate of metabolism.

Delzenne et. al. reports that dietary triacylglycerols (lipids) are transported from lymph to the blood as chylomicrons and then hydrolyzed by lipoprotein lipase. (Am. J. Nutr 2001, 73, 456S-8S; PTO-892). Delzenne identifies fatty acid synthase as the most sensitive to nutrients and hormones. Delzenne further notes that the addiction of

oligofructose and other nondigestable carbohydrates to the diets of rats can decrease lipogenesis in the liver by lowering the activity of key enzymes regulated only through modifications of gene expression. (Conclusions). It is not clear how the instant compositions can regulate enzymes that are only regulated through gene expression. Furthermore, a compound that can act to lower the activity of an enzyme is very unlikely to be able to increase the activity of the same enzyme. Nothing in the specification shows an ability of the instant compositions to both lower as well as increase the amount of lipids in blood. Furthermore, nothing in the specification shows an ability for the instant compositions to increase as well as lower the rate of metabolism.

The skilled artisan would view that regulating t the amount of lipids in human body or regulating the metabolism of lipoproteins in a subject including increasing as well as lowering the amount of lipid in blood and lowering as well as increasing the metabolism.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to achieve methods of regulating the condition of skin.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation, "derivative" in these claims render claims herein indefinite. The recitations, "derivative" of the compounds are not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "derivative" of compounds herein. One of ordinary skill in the art would clearly recognize that the recitations "{→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Kubolta et. al. (WO 01/90338, Publication Date 11/29/2001; PTO-892;). English Equivalent, U.S. Patent No. 7,192,746 is used *in lieu* of translation.

Kubolta et. al. discloses the synthesis of the cyclotetrasaccharide, cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}. (Abstract, Example A-1 to A-5, Columns 55-58). Kubolta further discloses a composition comprising said cyclic tetrasacchirde, (100 parts by weight), mineral, sodium chloride and potassium chloride, magnesium sulfate in preparation for fluid diet. (Example B-18, Column 65, lines 20-40). The example provides for a one-bag product mixture (25 grams), which can be dissolved in 150-300 ml water for a fluid diet, which is considered a unit dosage form. Kubolta further discloses sodium L-ascorbate, vitamin E and trehalose in composition comprising cyclic tetrasaccharide. (Example B-18, Column 65, lines 20-40). Kubolta further discloses several examples of compositions comprising said cyclostetrasaccharide and one or more of the ingredients of claims 2-14 herein. (Examples B1-B25; Columns 60-68). The amounts of the cyclic tetrasaccharide compound disclosed in the examples are considered sufficient to effect lipid lowering. Furthermore, since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Note that, the recitation "a lipid-regulating agent" is considered an intended use. The "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed.

As such, claims 17 is deemed anticipated by Kubolta et. al.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/15/07

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